

Exhibit C

GENERAL REPORT OF BARRY SCHLAFSTEIN, M.D., F.A.C.O.G
REGARDING THE PROLIFT AND PROLIFT +M

The following is my general report regarding the Prolift and the Prolift+M. The opinions expressed are based on my education, training, knowledge, experience, review of medical literature, attendance at medical meetings, and discussions with colleagues, and is based on information I have reviewed as part of my continuing medical review, the materials cited in this report, and information I have available to me, as set forth in Exhibit A to this report. It is my practice to regularly review medical information, attend and/or participate in medical meetings and consultations with my colleagues as part of my continuing medical education and experience. Accordingly, I reserve the right to add to or modify the opinions set forth in this report as information becomes available to me. All of my opinions expressed in this report are held to a reasonable degree of medical and scientific certainty.

I. Background, Training and Experience

In 1991, I completed my chief residency at The Johns Hopkins Hospital, in Baltimore, Maryland, after completing my internship and residency also at The Johns Hopkins Hospital. I obtained my M.D. degree, and received AOA membership honors from the University of Miami School of Medicine in 1987. In 1983, I received my B.S. degree, with honors in Nutritional Sciences from Cornell University in Ithaca, New York. I am board-certified by the American Board of Obstetrics & Gynecology in both Obstetrics & Gynecology (1993) and in Female Pelvic Medicine & Reconstructive Surgery (2013). I am licensed to practice medicine in Georgia, Florida and Maryland. I am a Fellow in the American College of Obstetrics & Gynecology, a member of the American Urogynecological Society (AUGS), The Georgia Obstetrical and Gynecological Society, and various other medical organizations. After completing my rotation as Chief Resident at Johns Hopkins in 1991, I joined a private practice

specializing in obstetrics and gynecology in Miami, FL, and in 1996 joined a private OB/GYN practice in Savannah, Ga. In 1997, I started my own practice specializing in OB/GYN and sub specializing in Female Pelvic Medicine and Reconstructive Surgery (aka Urogynecology) in Savannah, and have continued that practice to the present time. My practice includes general gynecological care, pelvic floor reconstruction, treatment of urinary incontinence and female pelvic organ prolapse, and 3D laparoscopic gynecological surgery. Since 2013, I have also served as Clinical Assistant Professor for the Medical College of Georgia. Because of my training and expertise, I am often referred patients by my colleagues, particularly when surgery is needed to treat complicated gynecologic maladies, and am often asked to instruct other obstetrician-gynecologists in the specialized area of female pelvic medicine and reconstructive surgery. My education and training is set forth in my curriculum vitae attached to this report as Exhibit B which also includes some of my past publications and presentations.

As a result of my training and education, I am aware of and can attest to how physicians are trained and what information is provided during such training. Moreover, because of my continuing medical education, review of medical literature, discussions with colleagues, attendance and participation in medical meetings and teaching other physicians, I am familiar with and can attest to how physicians obtain information that they rely on in performing surgical procedures, and the manner in which they apprise themselves of advances in medicine relevant to the practice of pelvic medicine. I have studied, seen and experienced, and thus can testify to, the various revolutionary innovations in this area of medicine which have improved available medical options for treatment of pelvic floor dysfunction and which have improved the quality of life available to women who suffer from these conditions.

I have substantial experience in treating pelvic floor dysfunction, including both non-surgical and surgical treatment of pelvic organ prolapse (POP) and incontinence, including specifically stress urinary incontinence (SUI). In treating conditions associated with pelvic organ prolapse (POP), I have prescribed non-surgical treatments including the use of pessaries, behavior modification, and physical therapy. Surgical options I have performed in treating POP have included: native tissue colporrhaphy, mesh augmented colporrhaphy, sacrospinous apical vaginal vault suspension, and sacrocolpopexy. Consequently, I can provide testimony as to the relative risks and benefits of such procedures, the relative efficacy of such procedures, potential complications of such procedures, how patients respond to such treatments, and the relative satisfaction patients have with their respective treatments.

With respect to the treatment of SUI, non-surgical options that I have administered and/or prescribed include: Pelvic floor muscle training, pessary use, and rarely the use of medication. Surgical procedures for SUI that I have performed at various times in my career include: anterior colporrhaphy, high Kelly urethral plication, Burch colposuspension, mid-urethral sling procedures utilizing synthetic mesh, and urethral bulking agents.

I have performed more than 630 trans-vaginal mesh augmented colporrhaphy procedures. In treating POP for many years, I have implanted various manufacturers' synthetic mesh products, including Gynemesh PS, Prolift, and Prolift +M. I am familiar with the substantial body of peer-reviewed published medical literature regarding Prolift mesh products, (including Gynemesh PS, Prolift, and Prolift+M) which demonstrate the safety and efficacy of these products and on which I rely for my opinions that these products are safe and effective for treating POP. My preferred choice for treating SUI has been and continues to be Ethicon's TVT-O, TVT-Abbrevio, and TVT-Exact inasmuch as I believe them to be safe and effective products

for surgically treating this condition. I am familiar with the TVT-R product as well and the substantial body of peer-reviewed published literature regarding the TVT products which demonstrate that these products are safe and effective in treating SUI. I have implanted more than 950 TVT products listed above.

In addition to utilizing the Ethicon products mentioned above, I have also managed complications associated with pelvic mesh procedures, often involving products manufactured by other device manufacturers. I can, therefore, testify regarding the contributing causes and appropriate treatments for such complications. Similarly, because I have been trained to perform many of the procedures available to treat pelvic floor disorders, I understand, and, if asked, can attest to the advantages and potential complications associated with each procedure, and how to avoid or minimize the risks of such complications, if possible, and how best to approach resolution of complications when they do occur.

II. Consulting Fees and Testimonial History

I am paid \$500.00 per hour for my time in these cases.

I have not testified as a retained expert witness in any matters in the past four years.

III. Materials Reviewed in Compiling this Report

In addition to the materials previously referenced in this report which serve as the basis for my opinions in this case, I have also reviewed the IFUs and Surgical Technique Guide for Ethicon's various mesh devices, as well as Surgeon's Resource Monographs, Professional Education slides, DVD's, animations and surgical videos, Patient Brochures, and other professional education materials relating to Ethicon's mesh devices, including the devices specifically at issue in this case.

IV. General Information

Pelvic organ prolapse (POP) is a condition where the muscles and ligaments supporting a woman's pelvic organs stretch, weaken, and attenuate, causing these organs to herniate into the vagina. That pelvic organ prolapse is a serious problem is indisputable, as evidenced by the fact that countless patients seek medical care annually for this condition, 225,000 women annually elect surgical treatment for correction of the problem, and 7%-19% of women will undergo a surgical repair for prolapse in their lifetime. (Norton P, Univ Utah EurekAlert Public Release: 15-May-2013). At a minimum, symptoms of the condition can be a bothersome nuisance to a patient, including a feeling of pressure or fullness in the vagina, bladder or rectum, and the feeling of a bulge in the vaginal area. As the condition progresses patients suffer increasing pain and discomfort, dyspareunia, and limitation of physical activity. Pelvic organ prolapse can alter a woman's self image and self esteem, and ultimately the condition can become incapacitating for the patient.

Anatomy

The human female pelvic visceral organs (bladder, uterus, rectum) are supported primarily by the levator ani pelvic floor muscle complex, and secondarily by surrounding fascial fibro-elastic connective tissue including the endopelvic fascia, uterosacral ligaments, and cardinal ligaments. The levator ani pelvic floor muscles remain in a physiological state of tonic contraction, and typically relax only voluntarily at the time of voiding and defecation, and involuntarily at the time of parturition. With normal adequate pelvic muscle tone, there is minimal strain on the fascial layers, and the pelvic organs remain well supported.

Pathophysiology

POP is associated with prior vaginal childbirth, aging, menopause, obesity, prior hysterectomy, and possibly heavy lifting. (Olsen, Obstet Gynecol 1997; Clark, AJOG 2003–

307). In the early stages of prolapse, pelvic floor muscles weaken and there is increased tension on the endopelvic fascia, uterosacral ligaments, and cardinal ligaments. Before there is irreversible damage to the connective tissue supportive structures, strengthening of the pelvic floor muscles with exercise may prevent further progression of disease. As the prolapse progresses, and the pelvic floor muscles become further weakened and dysfunctional, strain on the endopelvic fascia will cause weakening, attenuation, and ultimately can result in rupture of these connective tissue structures. With inadequate pelvic muscular and connective tissue fascial support, the pelvic organs prolapse, or herniate into the vagina. At this point non-surgical treatment with a silastic vaginal support device (pessary), or surgical correction is required. There are no FDA-approved medications available to treat this condition.

POP herniations are characterized by location. Anterior endopelvic fascial defects typically involve the bladder and are commonly referred to as a cystocele. Posterior endopelvic fascial defects involve rectal or small bowel herniation and are commonly referred to as a rectocele or enterocele. Apical herniation involves weakening of the uterosacral and cardinal ligaments, and causes the uterus and cervix to prolapse, and is called uterine prosidencia. Apical herniation in the post-hysterectomy patient causes the apical vaginal vault to herniate, and it is commonly referred to as vault prolapse, and may include an anterior or posterior enterocele. Many specialists in the field of FPMRS feel that there is always an apical component in advanced prolapse, when the leading edge of the prolapse falls at or below the hymeneal opening.

Non-Surgical Treatment

Pelvic floor muscle strengthening exercises may be recommended as first-line therapy for a motivated patient with early-stage disease, and as an adjunct to surgical therapy (Culligan P

2012 Obstet Gynecol;119:852-860) (Hagen S, Stark D, Cochrane Database Sys Rev 2011; 12:CD003882). Vaginal pessaries date back to ancient times, and should be offered to all patients with symptomatic POP, particularly those with later-stage prolapse. Limitations of the pessary include: difficulty properly fitting a patient; vaginal atrophy; poor compliance in patients with dementia or those with transportation issues; requisite removal for sexual function; and lack of desire for this treatment, particularly among younger patients. Pessaries require careful maintenance and follow-up, as their use can be associated with vaginal discharge and/or odor; worsening urinary incontinence or urinary retention; urosepsis; vaginal abrasions, erosions, and ulcerations; and rarely can cause bladder or rectal fistula, and small bowel entrapment (Aries BE, Ridgeway B, et al Int Urogynecol J 2008;19:1173-78).

Surgical Treatment

Native tissue colporrhaphy, dating back to Dr. Howard Kelly at The Johns Hopkins Hospital in the early 20th century, involves plication of attenuated or ruptured fascial connective tissue layers in either the anterior or posterior vaginal compartment. While a mainstay of surgical therapy for nearly a century, such techniques have proven to have limited efficacy and durability (Web AM, Walters MD, et al Am J Obstet Gynecol 2001; 185:1299-304: discussion 1304-6).

Augmented repairs

Augmenting colporrhaphy with graft material has developed as a direct result of the poor native tissue colporrhaphy outcomes described above. The general concept of augmenting repairs with graft material is an attempt to replace the attenuated endopelvic fascia with a more durable material. This concept borrows from the longstanding, successful use of graft material in hernia repairs performed in other areas of the body, such as the abdominal wall and inguinal

region, by general surgeons since the 1950's. Biological xenografts, including porcine dermis, porcine small intestine submucosa, and bovine pericardium have been studied for use in colporrhaphy. Such materials have demonstrated inferior anatomic outcome in comparison to mesh colporrhaphy (Maher CM, Baessler K, et al 5th ICI. Paris: Health Publications, Ltd; 2013).

Mesh Characteristics

Mesh augmented colporrhaphy with Gynecare Prolift and Prolift+M involves the use of Type I (Amid PK Hernia 1997;1:15-21) monofilament, light weight, loosely knit macroporous polypropylene mesh. The material is pre-sterilized, permanent, strong, and virtually inert to infection when appropriately placed (Cosson M Int Urogynecol J 2003). It is postulated that Type I mesh is resistant to infection because the large macroporous pore size of >75 microns allow for macrophage penetration. Larger pore size also enhances other favorable host responses, such as greater type III collagen deposition, greater capillary penetration, and greater attachment strength (Patel H, et al. Int Urogynecol J 2012; 23:669-679).

Mesh Augmented Surgical Treatments

When properly performed, mesh augmented colporrhaphy has proven to be minimally invasive, generally takes less than 60 minutes to perform, is very safe, and remarkably effective in restoring normal anatomy and function to the female suffering from POP. It is extremely important for the implanting surgeon to be skilled in this procedure, as proper dissection, precise mesh placement, and correct tensioning of the mesh implant is paramount for success. Details of the Prolift and Prolift+M procedural techniques can be reviewed in the product Instructions for Use (IFU), Surgical Technique Guide and Surgeons Resource Monograph, the Professional Education materials, and in my opinion these materials adequately warn of potential risks of the device. In a randomized trial published in The New England Journal, Altman, et al demonstrated

superior objective and subjective outcome with mesh augmented colporrhaphy, using the Gynecare Profit product versus native tissue colporrhaphy (Altman D, Vayrynen T, et al. NEJM 2011; 364:1826-36). They reported a 3.2% risk of re-operation for mesh exposure; increased rates of de-novo SUI; slightly increased OR time, bladder perforation, and estimated blood loss; with no difference in sexual function between the two group post-operatively.

Overall, Gynemesh PS and Prolift have been studied in several randomized controlled trials which demonstrate significant anatomic, subjective and quality of life improvements. (Carey M, et al. BJOG 2009;116:1380-6; Withagen MI, et al. Obstet Gynecol. 2011;117:242-50; Sokol AI, et al. Am J Obstet Gynecol. 2012; 206:86.e1-9; Halaska M, et al. Am J Obstet Gynecol. 2012; 207:301.e1-7; El-Nazer MA, et al. Arch Gynecol Obstet. 2012; 286:965-72; Qatawneh A, et al. Gynecol Surg 2013; 10:79–85; Svabik K, et al. Ultrasound Obstet Gynecol. 2014; 43:365-71; Dos Reis Brandão da Silveira S, et al. Int Urogynecol J. 2015; 26:335-42). These and other studies do not show a statistically significant difference in post-operative or de novo dyspareunia, pelvic pain, change in sexual function, or change in total vaginal length (TVL) compared to native tissue prolapse repair. (Dietz and Maher. Int Urogynecol J. 2013; 24:1853-7; Lowman JK, et al. Am J Obstet Gynecol. 2008; 199:707.e1-6). Rates of surgical intervention for mesh exposure, infection and tissue contraction have also been reported to be low. (de Landsheere L, et al. Am J Obstet Gynecol. 2012; 206:83.e1-7; Benbouzid S, et al. Int J Urol. 2012; 19:1010-6). Prolift +M has also demonstrated efficacy and safety in the treatment of pelvic organ prolapse. (Milani AL, et al. Am J Obstet Gynecol 2011; 204:74.e1-8; Milani AL, et al. Int Urogynecol J 2012; 23(Suppl 2):S128-129). A comparative study showed similar improvements in sexual function with Prolift +M and Prolift at 12 months. (Bhatia N, et al. FPMRS 2012; 18(Suppl 1):S20). An analysis of reoperation rates for Prolift and Prolift +M

were also similar. (Quemener J, et al. 2014; Eur J Obstet Gynecol Reprod Biol. 2014; 175:194-8).

Sacrocolpopexy is a mesh augmented apical vaginal vault suspension dating back to the 1960's, which requires entry into the intraperitoneal cavity. I perform this procedure in appropriately selected patients using a 3-D video laparoscopic approach. While this procedure provides excellent apical anatomic support, it typically requires significantly longer operative time than transvaginal mesh repairs, has greater potential for visceral organ injury, including a bowel obstruction rate of 1.1%, and has an associated mesh erosion rate of 3.4% (Nygard IE, McCreery R et al. Obstet Gynecol 2004; 104:805-23).

The patient for whom I recommend evaluation and surgical treatment with transvaginal mesh includes the symptomatic patient with pelvic organ prolapse who: has failed nonsurgical measures including pelvic floor muscle training and pessary use; has failed previous native tissue coporrhaphy; has prolapse beyond the hymen; or the patient with apical POP who is a poor surgical candidate for an abdominal approach to correction (i.e. sacrocolpopexy). This varies physician to physician based on their own judgment, experience and knowledge of their patients.

In the appropriately screened and selected patient, after a verbal and visual explanation of the procedure, and after appropriate informed consent, I will offer treatment with a mesh augmented colporrhaphy. Wherever possible we have maintained close ongoing surveillance of such patients after their mesh-augmented colporrhaphy procedure. Although as yet unpublished, our outcomes to date, have been favorable. The overwhelming majority of such patients have expressed extreme satisfaction with their experience, and not infrequently the results have been enthusiastically described as 'life- changing'.

All surgical options for treating POP carry risks of post-surgical complications. For example, abdominal surgery, in particular the ASC, can be more morbid than transvaginal surgery because it requires entry into the abdominal cavity, which can have significant, and in some instances life-threatening risks, including, among others: major vessel or visceral injury, sacral osteomyelitis, abdominal wound infection, abdominal hernia, adhesion formation, ileus and small bowel obstruction. Laparoscopic and robotic surgeries are associated with similar risks as described above, as well as the additional risks associated with steep Trendelenburg positioning, CO2 insufflation, and trocar, instrument, and energy related injuries.

Any pelvic surgery, including procedures to correct pelvic organ prolapse, carry the known and accepted risk of post-operative dyspareunia and chronic pelvic pain. Moreover, dyspareunia is a common complaint in women with prolapse that has never been surgically corrected. It has been reported that up to 64% of sexually active women attending urogynecology clinics suffer from female sexual dysfunction. (Dietz V, Maher C. Pelvic organ prolapse and sexual function. *Int Urogynecol J*. 2013 Nov; 24(11):1853-7.).

Dyspareunia, a difficult condition to treat, is often multi-factorial, involving vaginal atrophy, decreased libido, partner issues, and other causes, and may have a significant psychological component.

Tissue contraction, scarring and vaginal tightening/shortening are likewise known risks which can be associated with all gynecologic surgeries, including surgical procedures to treat prolapse.

It is my understanding that litigation-related claims have been made that polypropylene mesh such as that used in the Prolift and Prolift +M degrades in situ, contracts, results in particle loss, and is carcinogenic, and that these conditions cause clinical injury to patients in whom

such mesh is implanted. I am aware of no clinical data demonstrating that such conditions occur, and certainly there is no accepted, reliable data suggesting that even if such conditions exist, they have any clinical significance whatsoever. In fact, a recent study from the Mayo Clinic, undermines these claims entirely. See Linder B., et al., Evaluation of the local carcinogenic potential of mesh used in the treatment of female stress urinary incontinence, *Int Urogynecol J.* 2016.

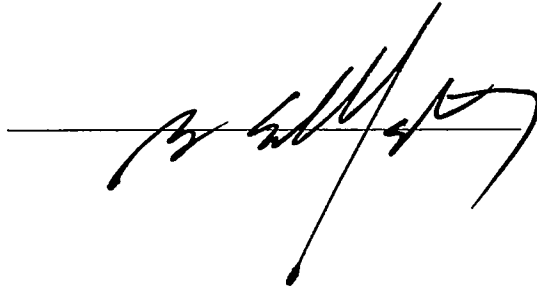
Given the number of patients in which polypropylene mesh has been implanted, as well as the voluminous studies, analyses and trials evaluating such pelvic mesh products, if any such conditions were occurring with any frequency and clinical significance, I would certainly expect published reports to exist. They do not. If these claims had any basis in science and medicine, I would not expect the most prestigious and respected professional organizations which govern the standards of gynecologic and urologic treatment of pelvic floor dysfunction, such as AUGS, AUA, IUGA and ACOG in 2015 to acknowledge a role for vaginal mesh augmentation in treatment of pelvic floor dysfunction. Assertions that these devices were “unreasonably dangerous” or “defective” as I understand are being alleged by some plaintiffs’ witnesses, are completely inconsistent with the position statements of these societies, the voluminous peer-reviewed published data relating to polypropylene pelvic mesh and my own clinical experience. It is my opinion that mesh products for repair of POP provide an important, safe and effective option for treating prolapse. And the data referenced and reflected in Exhibit A bear this out and support my opinion.

Physician Training

In addition to my clinical experience implanting Trans-Vaginal Mesh products, I also previously served as a clinical consultant for Ethicon for over five years. As a Gynecare pelvic

floor faculty member for the United States South East Prof Ed Region my responsibilities included: didactic lecturing, pelvic cadaver training, and live observational clinical demonstration on the use of these products. Our courses were tightly structured, and close attention was paid to the aptitude of each attending student. Appropriate indications for the use of these products, data regarding the efficacy and safety, complications, and our own unique experiences were thoroughly reviewed with attendees during these courses. Students were given access to, and encouraged to familiarize themselves with the unique Instructions for Use (IFU) booklet for each product. Attendees had excellent and adequate access to perform the procedures, often multiple times, on individual pelvic cadavers during such courses. Students were encouraged to seek further training and/or proctoring, if it was felt necessary, in order to safely perform these procedures after completion of the course. The responsibility for credentialing physicians to perform such procedures is under the domain of their respective and appropriate medical staff and hospital credentialing bodies. Color informational brochures, written in layman's terminology, are provided by the company to physicians who desire their use to aid in the preoperative patient educational process.

I reserve the right to amend my opinions if further facts and/or information necessitate supplementation.

A handwritten signature in black ink, appearing to read 'B. Schlafstein', is written over a horizontal line. The signature is stylized with a large, sweeping 'S' and a long, thin vertical stroke extending downwards from the end.

Barry Schlafstein MD, FACOG